ONE HUNDRED EIGHTH CONGRESS

Congress of the United States

House of Representatives

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November 19, 2003

The Honorable Thomas A. Scully
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Room 314-G
Washington, DC 20201

Dear Mr. Scully:

I am writing regarding a recent regulatory proposal by HHS that changes recordkeeping requirements under the Medicaid program. The proposal, *Medicaid Program: Time Limitation on Price Recalculations and Recordkeeping Requirements under the Drug Rebate Program*,[1] would allow drug manufacturers to destroy records that could otherwise be used to uncover and punish Medicaid fraud. The proposed rule establishes a requirement that manufacturers must keep these records for three years, but then allows these records to be eliminated.

The proposed rule has been opposed by the Attorneys General of over 40 states, as well as the acting HHS Inspector General.[2] I share these concerns. As written, the proposal would make it easier for drug manufacturers to defraud the Medicaid system, potentially costing taxpayers billions of dollars.

Although the proposed rule does contain a provision that would prevent drug manufacturers from destroying records if they are aware of an investigation into their products, it fails to take into account that drug manufacturers are often unaware of investigations until they have been underway for several years.

HHS appears to be unaware of the potential problems of the rule. Indeed, in conversations with HHS staff who wrote the proposed rule, my staff was told that HHS was unaware of any fraud cases that reached back more than three years. In fact, there are many of these cases, in which federal and state governments have recovered billions of dollars from fraudulent manufacturers.

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[1] 66 Fed. Reg. 51912 (Aug. 29, 2003).

[2] *Medicaid Records Proposal Criticized*, Associated Press (Nov. 10, 2003).

A November 2003 report prepared for the Taxpayers against Fraud Education Fund, which I have attached to this letter, highlights these cases.[3] The report identifies seven whistleblower cases in which the federal and state governments recovered $1.7 billion in penalties against drug manufacturers who overcharged the Medicaid system for prescription drugs. In all but one of these cases, the length of time between the beginning of the fraudulent schemes and the settlement with the drug manufacturer was over three years. Often, the period during which the fraud occurred was well over three years — in one case, up to 12 years.

The findings in this report make it abundantly clear that allowing drug manufacturers to destroy Medicaid pricing records after just three years could make it easier for an unscrupulous drug manufacturer to defraud the Medicaid system and to avoid full recompense if they are apprehended, with huge costs to taxpayers.

In light of these problems, I am asking that you rewrite this proposed rule. Presently, the False Claims Act has a statute of limitations of up to 10 years. Changes to the proposed rule that take this statute of limitations into account and require that manufacturers maintain records for at least a ten-year period would serve to adequately protect taxpayers and the Medicaid program.

Thank you for your attention to this issue. If there are any questions about this letter, my staff contact is Brian Cohen at (202) 225-5051.

Sincerely,

Henry A. Waxman
Ranking Minority Member

Enclosure

[3] Taxpayers against Fraud Education Fund, *Reducing Medicare and Medicaid Fraud by Drug Manufacturers: The Role of the False Claims Act* (Nov. 2003).